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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,275	04/08/2004	Hugh T. Conway	P-5690	8587

7590 05/04/2006

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EXAMINER

WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,275	<b>Applicant(s)</b> CONWAY, HUGH T.	
	<b>Examiner</b> Catherine N. Witczak	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/04/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

*Witczak*  
4/14/06

## DETAILED ACTION

### *Information Disclosure Statement*

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-9, 13-16, 19, 20, 22, 23, 25-32, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Mewby et al (EP 1,208,862).

Claims 1, 19, and 22: A shieldable needle assembly comprising: a needle cannula (2), a hub (5), a telescoping shield (3), a first biasing member (19); a lock (1 and 56) for releasably maintaining the shield in the fully retracted position; an actuator for releasing the lock; a needle holder (20) adapted for receiving a blood collection container (50); an actuator (4) activated by mating the hub (5) and blood collection tube (50), and a retaining member (57) engageable with the shield.

Claims 2 and 25: Mewby et al disclose in Figure 5 the actuator (4) including at least one actuating arm (15) slideably mounted on the hub for releasing the lock (paragraph 0015).

  
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Art Unit: 3767

Claims 3, 5, 26: Mewby et al disclose in Figure 7 the shield including a latch (11) and the housing including a detent (56) for releasably engaging the latch, wherein the latch and detent form the lock for releasably maintaining the shield in the fully retracted position.

Claim 4: Mewby et al disclose in Figure 4 a housing (20) projecting from the hub toward the distal end of the needle cannula (2).

Claims 6, 20, and 23: Mewby et al disclose in Figure 7 the retaining member including a retaining arm (56) slidably mounted on the hub, wherein the retaining member engages a retaining lug (11) on the shield (3).

Claims 7 and 8: Mewby et al disclose in Figure 3 a second biasing member (13) biasing the retaining arm (56) away from engagement with the retaining lug (11) after a period of time following activation of the actuator (paragraphs 0023 and 0024).

Claim 9: Mewby et al disclose in Figure 3 the hub (5) being adapted to mate with a needle holder (20), and the actuator (4) being activated by pressure applied through insertion of a sampling container within the needle holder (paragraph 0019).

Claim 13: Mewby et al disclose in Figure 5 the retaining member (57) including a retaining arm (56) slidably mounted on the hub, and wherein the retaining member engages the shield (3) after the actuator has disengaged the lock.

Art Unit: 3767

Claims 14 and 15: Mewby et al disclose in Figure 3 a second biasing member (13) biasing the retaining arm (56) away from engagement with the retaining lug (11) after a period of time following activation of the actuator (paragraphs 0023 and 0024).

Claim 16: Mewby et al disclose in paragraph 0019 the hub being adapted to mate with a needle holder, and the actuator being activated by pressure applied through insertion of a sampling container within the needle holder.

Claim 27: Mewby et al disclose a method of safety shielding a needle comprising: providing a needle assembly comprising a hub (5) mounted to a needle cannula (2) with a spring biased telescoping shield (3) mounted on the hub (5) and a retaining member (57) moveably mounted on the hub (5); providing a needle holder (20) adapted for receiving a blood collection tube (50); inserting a blood collection tube (50) into the needle holder, thereby engaging the retaining member with the telescoping shield and causing the retaining member to prevent the telescoping shield from being biased to a shielded position encompassing the needle cannula (paragraph 0019); and removing the blood collection tube from the needle holder, thereby disengaging the retaining member from the telescoping shield and causing the telescoping shield to be biased toward the shielded position encompassing the needle cannula (paragraph 0023, 0024, and 0028).

Claim 28: Mewby et al disclose releasably locking the telescoping shield (3) in a fully retracted position with a first lock (11 and 56) prior to engagement of the retaining member (57) with the telescoping shield, and releasing the first lock upon insertion of the blood collection tube (paragraph 0019).

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Art Unit: 3767

Claim 29: Mewby et al disclose in paragraph 0019 that releasing the first lock utilizes at least one actuating arm (15) slidably mounted on the hub for releasing the lock.

Claim 30: Mewby et al disclose in Figure 4 the actuating arm (15) extending within the needle holder (20) for engagement with the blood collection tube (50).

Claim 31: Mewby et al disclose in Figure 7 the shield including a latch (11) and the housing including a detent (56) for releasably engaging the latch, wherein the latch and detent form the lock for releasably maintaining the shield in the fully retracted position.

Claim 32: Mewby et al disclose in paragraph 0023 biasing the retaining member (57) away from engagement with the telescoping shield (3).

Claim 34: Mewby et al disclose in paragraph 0021 locking the telescoping shield in a shielded position encompassing the needle cannula.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 10, 11, 17, 18, 21, 24, and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Mewby et al as modified by Martin et al (US 4,887,998).

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Art Unit: 3767

Mewby et al disclose the claimed invention expect for the first biasing being a spring with a spring force less than the force required to disengaged the retaining arm away from the retaining lug and the second biasing member biasing the retaining arm away from engagement with the retaining lug upon withdrawal of the sampling container from the needle holder. Martin et al teach in column 3, lines 56-64 and column 3, lines 17-20 that it is known to use a first biasing being a spring with a spring force less than the force required to disengaged the retaining arm away from the retaining lug and the second biasing member biasing the retaining arm away from engagement with the retaining lug upon withdrawal of the sampling container from the needle holder to prevent reemergence of the needle from the sheath once the needle has been put to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Mewby et al with a first biasing being a spring with a spring force less than the force required to disengaged the retaining arm away from the retaining lug and the second biasing member biasing the retaining arm away from engagement with the retaining lug upon withdrawal of the sampling container from the needle holder as taught by Martin et, since such a modification would prevent reemergence of the needle from the sheath once to needle has been put into use.

Claim 12: Mewby et al disclose in paragraph 0021 the second lock securing the shield in the fully extended position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.



Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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C.

KEVIN SIRMONS  
PRIMARY EXAMINER

